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| 10/510,126        | 10/04/2004  | Gerardo Perez-Camargo | 115808-511          | 6573             |
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| EXAMINER          |             |                       |                     |                  |
| BARHAM, BETHANY P |             |                       |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/510,126

**Applicant(s)**

PEREZ-CAMARGO ET AL.

**Examiner**

BETHANY BARHAM

**Art Unit**

1615

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 38-49, 52, 53, 55 and 58-71 is/are pending in the application.
- 4a) Of the above claim(s) 38-47 and 61-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48, 49, 52, 53, 55 and 58-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Summary***

Receipt of Applicant's Response and claim amendments filed on 6/15/09 and 5/21/09 are acknowledged. Claims 38-53, 55 and 58-71 are pending. Claims 38-47 and 61-71 remain withdrawn. Claims 48-49, 52-53, 55 and 58-60 are rejected.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/15/09 has been entered.

Due to Applicant's claim amendments the previous 112, 102 and 103 rejections are hereby withdrawn.

## **NEW REJECTIONS**

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter,

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 58, which depends from claim 55 relating to whey protein and protease, states "wherein the fat transportation agent has a fatty acid profile specially-selected to improve absorption", while claim 59 states "wherein the fatty acid profile is polyunsaturated". The whey protein and protease do not have 'polyunsaturated' or a 'fatty acid profile' nor does the instant spec teach that they improve absorption, but rather that they 'help the formation of lipoproteins' (instant spec pg. 10, lines 14-15). The instant specification does teach that fish oil, prebiotic, probiotics, etc improve absorption and that polyunsaturates such as fish oils enhance absorption (pg. 10, lines 21-27). This is a new matter rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48-49, 52-53 and 58-59 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,759,933 ('933).

The instant claims are drawn to a nutrition management regimen comprising a dietary component for feeding regularly, according to predetermined directions, to a pet animal, the dietary component comprising a first pancreatic function promoter, a second

pancreatic function promoter, and an intestinal mucosa function-promoter in an amount effective to maintain, promote or enhance the capacity of the pet to digest lipid, wherein the intestinal mucosa function- promoter comprises an omega-3 fatty acid derived from fish oils, and wherein the first pancreatic function promoter is a pancreatic extract, and the second pancreatic function promoter is a gut pH modifier selected from the group consisting of a prebiotic, a probiotic and combinations thereof.

- '933 teaches a product comprising fish meat mixed with an oil and further consisting of proteolytic enzymes and/or protein digesting micro-organisms (abstract, claims 10, 13 and 16). '933 teaches mixtures of pancreatin (a proteolytic enzyme) and lactobacilli (a protein digesting micro-organisms, or instant spec teaches this is a probiotic pg. 12) and oils such as fish oil (col. 2, lines 45, col. 3, lines 1 and 10-30; Examples 26 and 29) (meeting the limitations of claim 48).
- '933 teaches adding egg or soybean (instant spec teaches these are emulsifiers and therefore liver function promoters pg. 13) (col. 2, lines 28 and 40-42) (meeting the limitations of claims 49 and 52-53).
- '933 teaches papain (col. 2, line 67) (a protease according to the instant spec pg. 10) (meeting the limitations of claim 55 and 58-59).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-49, and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0119237 ('237) in view of US 4,759,933 ('933).

- '237 teaches a probiotic food supplement directed to veterinary applications comprising fish oil, antioxidants and probiotic ingredients comprising one or more probiotic microorganisms and enzymes (abstract, claims 7, and 13). Examples 2 and 3 teach cod liver oil (a fish oil), enzyme (papaya extract) and probiotic bacteria and oligosaccharides (meeting the limitations of claim 48).
- '237 teaches compositions with vitamins such as tocopherol (instant spec teaches that this is a glutathione promoter pg. 13), taurine (liver function promoter), etc (Examples 1-3) (meeting the limitations of claims 49, 52-53).
- '237 does not teach the specific enzyme pancreatic lipase instant claimed.
- '933 teaches enzymes useful in food products include extracts from papaya (papain) or pancreas (pancreatin) (col. 2, line 63-col. 3, line 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '237 in view of '933. A skilled artisan would know how to substitute one enzyme papain of '237 for the specific enzyme pancreatin of '933 with predictable results because each is taught as useful in food products. Such a substitution of one enzyme for another is within the purview of the skilled artisan.

Claims 48-49, 52-53, 55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,210,718 ('718).

- '718 teaches a nutrient composition comprising proteins, fats such as fish oil (col. 7, lines 42), an enzyme such as lipase as a digestion aid (col. 8, lines 19-26), probiotics to benefit the gastrointestinal flora such as lactobacillis, etc (col. 8, lines 38-62) (meeting the limitations of claim 48).
- '718 teaches that the enzymes, microorganisms, etc promote enhance digestive activity, nutrient absorption or maturation of the gastrointestinal system as a whole (col. 11, lines 55-62).
- '718 teaches adding vitamins and minerals such as vitamin E (instant spec teaches that this is a glutathione promoter pg. 13) (col. 8, lines 28-38) (meeting the limitations of claims 49, and 52-53).
- '718 teaches that the proteins can be from whey (col. 7, line 24) (meeting the limitations of claims 55 and 58-60).
- '718 does not teach a single embodiment with all these components, but does teach that the components form a nutrient formulation for poultry and animals.

A reference is analyzed using its broadest teachings. MPEP 2123 [R-5].

"[W]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is

obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to rearrange the known components of '718 into a single formulation and obtain a nutrient composition for animals as disclosed by '718 that benefit the gastrointestinal flora, aids in digestion, etc to yield predictable results. Such a rearrangement is within the purview of the skilled artisan who is not an automaton.

Claims 48-49, 52-53, 55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,471,999 ('999) in view of EP 1 048 226 ('226) or US 6,576,667 ('667).

- '999 teach a pet milk powder as nutritional milk that results in reduced gastrointestinal intolerance (abstract). '999 teaches that the milk powder when administered in an effective amount with the nutritional composition reduces gastrointestinal intolerance and that it may further comprise one or more lipid source, protein source, vitamins and minerals, and teaches a specific aspect



which comprises lactose (of micro-organism origin), lactase (an enzyme), taurine, arginine and choline (claims 1-9; col. 2, lines 9-lines 26).

- '999 teaches omega fatty acids such as soybean and rapeseed oil and in Examples 1-2 (col. 3, lines 15-20).
- '999 teaches chicory fibers, inulin, fructooligosaccharides with the probiotic micro-organism have a symbiotic relationship for promoting beneficial effects (col. 4, lines 9-14) (according to the limitations of claim 48).
- '999 teaches including an alkali in the milk-based powder, which slows the pH drop in the gastrointestinal tract (col. 2, lines 53-55). '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40) (meets the limitations of claims 49, 52-53 and 55, 58-60 since whey protein, omega-3 and taurine are all taught).
- '999 teaches that the amount of nutritional composition is to be fed to a mammal each day depends of factors such as age, type of mammal (dogs and cats), and other nutritional sources (col. 4, lines 25-36).
- Examples 1 and 2 teach mixing the milk powder, galactosidase (lactase amino, an enzyme), vitamins, minerals, and soybean oil, and adding water to provide nutritional supplement to dogs and puppies or cats.
- '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by

improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40) (according to the limitations of claims 55 and 58-60).

- '999 does not teach omega fatty acids derived from fish oil or the specific enzyme lipase, but does teach an oil component and an enzyme.
- Example 1 of '226 teaches a formulation comprising whey protein concentrate, pancreatin (a known pancreatic extract or lipase), fish oil, soya oil, vitamins/minerals and various amino acids including glutamic acid, cystine and glycine (which are glutathione promoters).
- '667 Example 7 teaches a composition comprising lipase and an emulsifier mixed with fish oil.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '999 in view of '226 or '667. A skilled artisan would know how to substitute a known omega-3-fatty acid of rapeseed oil and a known enzyme of '999 for the specific the fish oil and lipase of '226 or '667 into the pet food composition of '999. It is within the purview of the skilled artisan to substitute one known omega fatty acid and one known enzyme for another with predictable results.

### ***Response to Arguments***

Applicant's arguments with respect to claims 48-49, 52-53, 55 and 58-60 have been considered but are moot in view of the new grounds of rejection necessitated by applicants' amendments.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-6175. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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